

INGREDIENTS: Black Cohosh (Powd. Ext. Cimicifuga) 0.0065 Gm. Wind Flower (Powd. Ext. Pulsatilla) 0.0065 Gm. Ferrous Sulfate U.S.P. Manganese Dioxide Thiamine Hydrochloride U.S.P. (Vit. B₁) 0.001 Gm."; and (front panel "½ OUNCE Rem-Al Emetic Brand of Fluid Extract of Ipecac-Alcohol 30% Distributed by REM-AL DRUG CO. 2 SUFFOLK STREET NEW YORK 2, N.Y."; (back panel) "DIRECTIONS Put 15 to 20 drops of REM-AL in a large drink of alcoholic beverage. Half hour later give a small drink using 15 to 20 drops of Rem-Al. NOTE: Use only as directed above and by directions accompanying bottle. CAUTION: Do not use in heart, liver, kidney, circulatory diseases, pregnancy, stomach ulcers, high blood pressure or serious disorder without consulting your physician."

CHARGE: 502(a)—the labeling of the articles contained false and misleading representations that the *Quik-Kap capsules* were an adequate and effective treatment for delayed or irregular menstruation, and that the *Rem-Al Emetic* was an adequate and effective treatment for drunkenness; and 502(j)—the *Rem-Al Emetic* was dangerous to health when used in the dosage prescribed, recommended, and suggested in its labeling.

PLEA: Guilty.

DISPOSITION: 1-15-60. \$1,000 fine, suspended sentence of 90 days in jail, and probation for 1 year.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6002. Grisovin tablets (2 seizure actions). (F.D.C. Nos. 43172, 43194. S. Nos. 56-794 P, 56-803 P.)

QUANTITY: 3 1,000-tablet btls. at Miami, Fla.

SHIPPED: Between 4-27-59 and 5-4-59, from New York, N.Y., by Overseas Pharmaceutical Co.

LABEL IN PART: "Grisovin 250 Mg. Griseofulvin Glaxo Laboratories, Greenford, England."

LIBELED: 6-19-59 and about 6-25-59, S. Dist. Fla.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 8-17-59. Default—destruction.

6003. Vitamin B₁₂ injection. (F.D.C. No. 40930. S. No. 67-040 M.)

QUANTITY: 144 10-cc. vials at Baltimore, Md.

SHIPPED: 9-18-57, from Chicago, Ill., by Maizel Laboratories, Inc.

LABEL IN PART: "Intramuscular 10 cc Intravenous VITAMIN B₁₂ INJECTION Cyanocobalamin U.S.P. 1000 mcg. Each cc. contains a sterile solution of 1000 micrograms Vitamin B₁₂ U.S.P. (Cyanocobalamin) in normal saline with 2% Benzyl Alcohol as preservative. * * * 28590."

RESULTS OF INVESTIGATION: Examination showed that each cubic centimeter of the article contained 1,039 micrograms of cyanocobalamin (vitamin B₁₂), 9.88 milligrams of sodium chloride, and a quantity of unidentified dissolved material.

LIBELED: 11-1-57, Dist. Md.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for *cyanocobalamin injection* set forth in the United States

Pharmacopoeia since it contained a substantial amount of unidentified dissolved material which is not permitted by the standard as an ingredient of *cyanocobalamin injection*; and 505(a)—the article, because of the presence of unidentified dissolved material, was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: Maizel Laboratories, Inc., claimant, filed an answer denying that the article was adulterated or a new drug as charged. The Government filed written interrogatories to which claimant objected in part. After a hearing, the claimant was required to answer all of the interrogatories but eight. Subsequently, the Government filed additional interrogatories which claimant answered. Thereafter, claimant having consented, on 8-10-59, a decree of condemnation was entered and the article was destroyed.

6004. Enerjol capsules. (F.D.C. No. 41276. S. Nos. 85-201/4 M.)

QUANTITY: 5,213 btl. of double strength capsules, and 2,733 btl. of single strength capsules, at Chicago, Ill., in possession of Owen Laboratories.

SHIPPED: 11-18-57 and 12-5-57, from Long Island City, N.Y.

LABEL IN PART: "60 (or other number) Capsules Lot No. 30019 ENERJOL DOUBLE STRENGTH Each Capsule contains: Thiamin Chloride 20 mgm. Riboflavin 10 mgm. Vitamin E (as D-alpha tocopherol acid succinate) 10 I. U. Vitamin B-12 Cobalamin conc. 10 mcgm. Iron (from ferrous gluconate) 20 mgm. Oyster Shell Powder 25 mgm. Royal Jelly 25 mgm. Iodine (from potassium iodide) 0.2 mgm. For use as a Dietary Supplement: One capsule daily." or "SINGLE STRENGTH Each capsule contains: Thiamin chloride 10 mgm. Riboflavin 5 mgm. Vitamin E (as D-alpha tocopherol acid succinate) 5 I. U. Vitamin B-12 Cobalamin conc. 5 mcgm. Iron (from ferrous gluconate) 10 mgm. Oyster Shell Powder 20 mgm. Royal Jelly 12.5 mgm. Iodine (from potassium iodide) 0.1 mgm. For use as a dietary supplement."

ACCOMPANYING LABELING: Circulars entitled "Owen Laboratories. The Enerjol Plan With Royal Jelly The Queen Bees Answer to Long Life" and "Discovered: New Wonder Capsule so Potent It Actually 'Combats Ills of Old Age' * * * Helps Put back Power Into Important Bodily Functions."

LIBELED: 12-9-57, N. Dist. Ill.; libel amended 12-19-57.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for glandular diseases, tiredness, sexual deficiency, nervous tension, dizziness, lack of sleep, loss of mental and physical ambition, lack of appetite, increasing longevity, and weakened, tired eyes; and 505(a)—the article was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: Owen Laboratories appeared as claimant and filed an answer denying that the drug was misbranded or a new drug. Thereafter, the Government filed written interrogatories against the claimant. On 4-30-58, the claimant requested additional time to answer the interrogatories, which was granted. Thereafter, on 5-8-58, the claimant filed objections to the interrogatories. Subsequently the Government filed a motion to have the objections stricken since additional time had not been granted for claimant to object to the interrogatories. The court thereupon, on 5-21-58, ordered that the